# **UK Patent Application**

(19)

(43) Date of A publication 06.03.1991

- (21) Application No 8919543.2
- (22)" Date of filing 29.08.1989

**Oswald Morton** 

**United Kingdom** 

(72) Inventor

(51) INT CL\* A61K 7/06

- erer: L
- (52) UK CL (Edition K) ASB BFC B822
- (71) Applicant Oswald Morton 5 St. Hilda's Close, Christchurch Avenue, London,
  - NW6 7NY, United Kingdom
- (74) Agent and/or Address for Service Bouit Wade & Tennant 27 Furnival Street, London, EC4A 1PQ,

- (56). Documents cited GB 1354446 A The Extra Pharmacopoeia (Martindale), 29th Edition, pages 931, 934, 1006
- (58) Field of search UK CL (Edition K) A5B BFC INT CLI A61K Online databases: WPI

- (54) Anti-dandruff composition
- (57) The invention relates to an anti-dandruff composition comprising an anti-dandruff agent and a keratolytic agent. The anti-dandruff agent may be zinc pyrithione or selenium sulphide. The keratolytic agent may be urea or salicylic acid.

#### ANTI-DANDRUFF COMPOSITION

The invention relates to an anti-dandruff compostion which is preferably in the form of a cream or gel.

Dandruff is a condition of the scalp in which there is an increase in the rate at which skin cells are formed and shed. In addition at the surface of the scalp the cells tend to stick together so that, when they are shed, they form visible white flakes (dandruff), in contrast to the much smaller and generally invisible flakes that are being shed all the time from skin surfaces, including a scalp which is not exhibiting dandruff.

It has been appreciated by the inventor that dandruff poses two problems, both of which need treating; the first is an increased rate of formation of the shedded cells, and the second is the agglomeration of the shedded cells to form the visible flakes.

It is the case at this time these two problems are treated separately. Agents such as selenium sulphide or zinc pyrithione are used to decrease the rate of formation of the shedded cells, and shampoos are used to wash off the shedded cells. It is known, of course, to combine these actions and there are available commercially shampoos which contain, for example, zinc pyrithione. It is believed that there are no compositions which are available which combine treatments for the two problems, especially in compositions to be used prior to the use of a shampoo.

It has been surprisingly discovered that a new and useful composition to deal with the problems described above comprise an anti-dandruff agent and a keratolytic agent, especially zinc pyrithione and urea. The anti-dandruff agent such as zinc

5

10

15

20

25

30

pyrithione performs its known function of reducing the rate of formation of cells at the surface of the scalp, i.e. reducing the cell turnover and inhibiting pityrosporum ovale, and the keratolytic agent, such as urea, brings about the dispersal of cells from the matted desquamated cells.

zinc pyrithione and other anti-dandruff agents such as selenium sulphide have been used in shampoos for many years and are considered to be effective and safe. Urea is one keratolytic agent which has been widely used in dermatological preparations and it has proved effective and safe. It is believed, however, that the present invention involves the first proposal to apply an agent such as urea to the scalp, in compositions with an anti-dandruff agent, such as zinc pyrithione.

According to the present invention there is provided an anti-dandruff composition comprising an anti-dandruff agent and a keratolytic agent, which keratolytic agent is of such a type or is present in such an amount that the composition has a mild keratolytic effect which does not adversely affect the scalp. Preferably the anti-dandruff agent is zinc pyrithione, but other anti-dandruff agents, especially selenium sulphide, may be used. The preferred keratolytic agent is urea, but effective compositions in accordance with this invention may contain at least one other keratolytic agent, such as salicylic acid.

The present invention also includes a method of reducing dandruff which involves applying to the scalp an anti-dandruff agent and a keratolytic agent.

It is preferred that a composition in accordance with this invention is in the form of a water-miscible cream or gel. A composition comprising 0.75% zinc pyrithione and 5% urea, for

5

10

15

20

25

30

example, is to be applied to the scalp twice a week and the composition left in place for, say, five minutes before removal, e.g. by shampooing. The use of a composition in accordance with the invention reduces the need for frequent shampooing which is often undertaken by dandruff sufferers with consequential dryness and brittleness of the hair.

An anti-dandruff agent which is not water soluble may be "solubilised" in an appropriate vehicle, such as polyethylene glycol, and a gel produced by using a suitable thickening agent such as sodium acrylate.

It has been found that gel of viscosity of 5000 cps is suitable for application to the scalp, and gel compositions may have viscosities of from 2000 to 8000 cps.

The Marine

It is to be understood that the preferred compositions in accordance with this invention do not contain a shampoo. Effective anti-dandruff treatment can, however, be obtained by the use of a composition in accordance with this invention which also contains a shampoo; in use a composition may be applied to the scalp and left in place for up to five minutes and thereafter rinsed away with water. A further shampoo with a small quantity of shampoo may also be undertaken.

In compositions in accordance with the invention the zinc pyrithione may be present in an amount of from 0.25 to 2.5% by weight, preferably from 0.5 to 1.5% and even more preferably from 0.5 to 1% by weight. Urea may be present in a composition in amounts of from 1 to 20%, preferably 3 to 20% and even more preferably from 3 to 8% by weight based on the weight of the composition. Furthermore when the anti-dandruff agent is selenium sulphide, it may be present in an amount of from 1 to 5%, and preferably

10

15

20

25

30

from 1.5 to 3.5% by weight based on the weight of the composition. When salicylic acid is the keratolytic agent, it may be present in the composition in an amount of from 1 to 8%, preferably from 3 to 7% by weight based on the weight of the composition.

It is preferred that compositions in accordance with this invention are substantially neutral in pH, and also that they contain triethanolamine or the like.

The following is a description by way of example of compositions in accordance with the invention.

### Example 1

15

5

Zinc Pyrithione	0.75	% W/W
Urea	5.00	% W/W
Cabopol 934	1.00	% W/W
Triethanolamine	1.00	% W/W

20

25

The composition was prepared by dissolving the urea in ?ml of water to provide a clear solution on stirring. The zinc pyrithione was added with stirring provided by a Silverson mixer fitted with an air guard and a pale brown milky suspension resulted. Thereafter the Carbopol 934 was added slowly into the vortex created by the Silverson mixer to provide a brown emulsion. The composition was allowed to stand for 10 minutes and entrapped air released. Finally the triethanolamine was stirred in gently with a spatula to produce an anti-dandruff gel.

### CLAIMS:

- An anti-dandruff composition comprising an anti-dandruff agent and a keratolytic agent, which
  keratolytic agent is of such a type or is present in such an amount that the composition has a keratolytic effect which does not adversely affect the scalp.
- 2. A composition as claimed in claim 1 wherein 10 the anti-dandruff agent is zinc pyrithione.
  - 3. A composition as claimed in claim 1 wherein the anti-dandruff agent is selenium sulphide.
- 4. A composition as claimed in any one of the preceding claims wherein the keratolytic agent is urea.
- 5. A composition as claimed in claim 2 wherein the zinc pyrithione is present in an amount of 0.5 to 1.5 percent by weight based on the weight of the composition.
- 6. A composition as claimed in claim 5 wherein the amount of zinc pyrithione is from 0.5 to 1% by weight.
- 7. A composition as claimed in any one of the preceding claims wherein the keratolytic agent is urea which is present in an amount of from 3 to 20% by weight based on the weight of the composition.
- 8. A composition as claimed in claim 7 wherein the urea is present in amount of from 3 to 8% by weight.

- 9. A composition as claimed in claim 1 wherein the anti-dandruff agent is zinc pyrithione or selenium sulphide and the keratolytic agent is salicylic acid present in an amount of from 1 to 10% by weight based on the weight of the composition.
- 10. A composition as claimed in claim 9 wherein the salicylic acid is present in an amount of from 3 to 8% by weight.
- 11. A composition as claimed in claim 1 and substantially as hereinbefore described in any one of the examples.
- 12. A method of treating dandruff on the scalp, wherein there is applied to the scalp an anti-dandruff agent and a keratolytic agent.
- 13. A method as claimed in claim 12 wherein 20 the anti-dandruff agent is zinc pyrithione and the keratolytic agent is urea.

25

5

30

THIS PAGE BLANK (USPTO)

O.L

# This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:
☐ BLACK BORDERS
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
☐ FADED TEXT OR DRAWING
☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
☐ SKEWED/SLANTED IMAGES
☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
☐ GRAY SCALE DOCUMENTS
☐ LINES OR MARKS ON ORIGINAL DOCUMENT
☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

### IMAGES ARE BEST AVAILABLE COPY.

OTHER:

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

## THIS PAGE BLANK (USPTO)